IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG, and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. APOTEX INC., et al., Defendants.	C.A. No. 18-088 (LPS) CONSOLIDATED [redacted] Public Version Filed August 26, 2020

DEFENDANTS SANDOZ INC. AND LEK PHARMACEUTICALS D.D.'S OPENING BRIEF IN SUPPORT OF THEIR MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS AS TO COUNTS V-VI OF PLAINTIFFS' THIRD AMENDED COMPLAINT AND TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

Of Counsel:

Mark H. Remus
Laura A. Lydigsen
Jason Schigelone
Jieun Lee
BRINKS GILSON & LIONE
455 North Cityfront Plaza Drive, Suite 3600
Chicago, Illinois 60611-5599
mremus@brinksgilson.com
llydigsen@brinksgilson.com
jschigelone@brinksgilson.com
jlee@brinksgilson.com
Phone: (312) 321-4200

HEYMAN ENERIO GATTUSO & HIRZEL LLP

Dominick T. Gattuso (#3630)
300 Delaware Ave., Suite 200
Wilmington, DE 19801
dgattuso@hegh.law
Phone: (302) 472-7311

Counsel for Defendants Sandoz Inc. and Lek Pharmaceuticals d.d.

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I. INTRODUCTION

On June 26, 2020, the Court granted Sandoz's motion for dismissal of Counts I-IV of Plaintiffs' complaint because Sandoz withdrew its prior Paragraph IV certifications for the four polymorph patents covered by those counts and replaced them with Paragraph III certifications. After briefing was complete on Sandoz's prior dismissal motion but before the hearing back in December 2019, Sandoz submitted a Paragraph III certification for a fifth patent-in-suit, U.S. Patent No. 9,125,910 ("'910 patent"), which had previously been the subject of a section viii statement by Sandoz.

In light of Sandoz's Paragraph III certification for the '910 patent, Plaintiffs' claims for infringement of the '910 patent should be dismissed for the same reasons as the four previously-dismissed polymorph patents. Pursuant to Sandoz's Paragraph III certification for the '910 patent, Sandoz is not seeking approval of its ANDA before the date the '910 patent expires and cannot infringe the '910 patent. Thus, Plaintiffs cannot state a claim for which relief can be granted and Counts V-VI should be dismissed without prejudice under Fed. R. Civ. P. 12(c) just like the polymorph patents that the Court has already dismissed.

Counts V-VI should also be dismissed for lack of subject matter jurisdiction because no case or controversy exists with respect to the '910 patent; a patent that has never been the subject of a Paragraph IV certification by Sandoz. When the '910 patent was added to this suit, Plaintiffs argued that jurisdiction existed by virtue of the case or controversy over the polymorph patents, which Sandoz originally challenged via Paragraph IV certifications. With the dismissal of the polymorph patents, that case or controversy no longer exists. Because no case or controversy exists for the '910 patent, Counts V-VI should be dismissed without prejudice under Fed. R. Civ. P. 12(b)(1).

II. NATURE AND STAGE OF PROCEEDINGS

Sandoz Inc. and Lek Pharmaceuticals d.d. (collectively, "Sandoz") constitute one of nine remaining defendant groups in this consolidated Hatch-Waxman litigation involving vortioxetine hydrobromide tablets. As of the filing of this motion, various combinations of ten patents are asserted against each defendant group. On June 26, 2020, the Court dismissed without prejudice Plaintiffs' counts alleging infringement of four of the six patents asserted against Sandoz. D.I. 813, D.I. 814. Sandoz's counterclaims for those four patents were likewise dismissed without prejudice. D.I. 813, D.I. 883, ¶¶ 35-102. Plaintiffs continue to maintain assertions of infringement against Sandoz for two patents, the '910 patent and U.S. Patent No. 9,278,096 ("'096 patent"). Expert discovery closes September 25, 2020, and trial is set for January 2021. D.I. 829, Scheduling Order.

III. STATEMENT OF FACTS

A. Sandoz's Withdrawal of its Paragraph IV Certifications and Submission of Paragraph III Certifications for the Polymorph Patents

On January 30, 2018, Plaintiffs filed suit alleging that Sandoz Inc.'s ANDA No. 210993 infringes three related patents, U.S. Patent Nos. 8,722,684 ("'684 patent"), 8,969,355 ("'355 patent"), and 9,227,946 ("'946 patent"). On May 9, 2019, Sandoz consented to the filing of a First Amended Complaint adding allegations of infringement for a fourth related patent, U.S. Patent No. 9,861,630 ("'630 patent"). D.I. 246. For each of these four "polymorph patents," Sandoz Inc.'s ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that the patent was not infringed, invalid, and/or unenforceable.

As explained in greater detail in Sandoz's brief in support of its motion to dismiss the polymorph patents (D.I. 416 at 5-7), Plaintiffs subsequently listed several additional patents in the Orange Book and obtained a substantial patent term extension ("PTE") for one of two

compound patents for which Sandoz has consistently maintained Paragraph III certifications. Plaintiffs' subsequently-listed Orange Book patents included the '910 and '096 patents.

On June 26, 2019, Sandoz withdrew its Paragraph IV certifications for the four polymorph patents and submitted Paragraph III certifications. [redacted][1] Those Paragraph III certifications mean that, as a matter of law, the FDA cannot approve Sandoz Inc.'s ANDA No. 210993 until after the last crystal polymorph patent expires, i.e., June 30, 2031. *See* 21 U.S.C. § 355(j)(5)(B)(ii). As of June 26, 2019, Sandoz has not maintained any Paragraph IV certifications for ANDA No. 210993.

Notwithstanding Sandoz's withdrawal of its Paragraph IV certifications, the parties were not able to reach agreement on terms for dismissal. *See* D.I. 416 at 7-8 (summarizing negotiations). As a result, on September 13, 2019, Sandoz filed an opposed motion for partial judgment on the pleadings in which it sought dismissal without prejudice of the counts of Plaintiffs' Second Amended Complaint alleging infringement of the four polymorph patents. D.I. 415, 416, 432.

B. Sandoz's Submission of a Paragraph III Certification for the '910 Patent

The '910 patent is one of four patents that Plaintiffs listed in the Orange Book well after this litigation began, which contain claims directed to methods of treatment with vortioxetine for uses other than vortioxetine's sole FDA-approved indication, major depressive disorder ("MDD"). The other three "non-MDD" patents are U.S. Patent Nos. 9,125,908, 9,125,909, and the '096 patent.

[redacted]

[1] All "Ex. _" references are to the Declaration of Jieun Lee submitted herewith.

[redacted] Plaintiffs sought and obtained leave to amend their complaint to assert two of the non-MDD patents, the '910 and '096 patents, against Sandoz. D.I. 225, 260. Sandoz then moved for certification to file an interlocutory appeal of the Court's decision granting Plaintiffs leave to amend to add counts for infringement of the '910 and '096 patents. D.I. 378. On November 15, 2019, the Court denied Sandoz's request for leave to file an interlocutory appeal. D.I. 542.

On December 4, Sandoz withdrew its section viii statement for the '910 patent and instead submitted a Paragraph III certification under which, as a matter of law, the FDA cannot approve Sandoz Inc.'s ANDA No. 210993 until after the '910 patent expires.[2] *See* 21 U.S.C. § 355(j)(5)(B)(ii). Sandoz's briefing on its motion to dismiss was already complete by the time Sandoz withdrew its section viii statement for the '910 patent, so the '910 patent was not included in that earlier-filed motion. D.I. 432. However, Sandoz promptly informed the Court of the amendment to its certification for the '910 patent. D.I. 605. At the December 18, 2019 oral hearing on the pending motion to dismiss, Sandoz again flagged for the Court that Sandoz's certification for the '910 patent was now the same as the polymorph patents and argued that it should also be dismissed. Ex. D, Hr'g Tr. 52:24-53:16. Plaintiffs agreed at the oral hearing that the '910 patent should be grouped with the related polymorph patents and argued only that the [redacted], was situated differently. *Id.* at 72:9-13.

[2] The '910 patent expires on June 15, 2027, which is prior to the June 30, 2031 expiration of the latest-expiring of the polymorph patents, the '684 patent, for which Sandoz submitted a Paragraph III certification in June 2019. Ex. C, OB listing.

C. Dismissal of the Polymorph Patents and Subsequent Discussions Regarding the '910 and '096 Patents

On June 26, 2020, the Court granted Sandoz's motion for partial judgment on the pleadings for the polymorph patents and dismissed those four patents and Sandoz's counterclaims for them without prejudice.[3] D.I. 813, 814. With the dismissal of the polymorph patents, the only allegations of infringement remaining in the case against Sandoz concern the two asserted non-MDD patents, the '910 and '096 patents. D.I. 883, ¶¶ 35-102.

The Court's Order granting Sandoz's motion to dismiss counts alleging infringement of the polymorph patents instructed the parties to meet and confer and to "submit a joint status report, advising the Court of their positions as to whether and how the case against the Sandoz defendants should now proceed." D.I. 814.

Pursuant to the Court's June 26 order, the parties met-and-conferred twice, after which Plaintiffs provided a draft proposal for a [redacted] Sandoz notified Plaintiffs that it would instead likely move to dismiss at least with respect to the '910 patent, and, on July 8, the parties submitted a joint status report stating their positions on whether the '910 and '096 patents should be dismissed. D.I. 839. On July 28, the Court issued an oral order stating that "Plaintiffs and/or

[3] Sandoz also moved for dismissal on the separate basis of lack of subject matter jurisdiction. The Court denied that request because Sandoz's original Paragraph IV certifications for the polymorph patents established a case or controversy and Sandoz had not established that its Paragraph III certification mooted that controversy given Sandoz's unwillingness to stipulate that it would not file a new Paragraph IV certification at a later date. D.I. 813, Op. 7.

the Sandoz Defendants may file a motion to dismiss any claims or counterclaims relating to the '910 and/or '096 patents, but the Court is not granting any relief at this time based on the status report and any limited argument that has been provided to date."[4] D.I. 875.

IV. LEGAL STANDARD

In the Third Circuit, Rule 12(c) motions are subject to the same standards as Rule 12(b)(6) motions. *See Turbe v. Government of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991). Under Rule 12(b)(6), a complaint that "fail[s] to state a claim upon which relief can be granted" must be dismissed. Fed. R. Civ. P. 12(b)(6). The moving party bears the burden of showing that the complaint fails to state a claim. *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000). In reviewing a motion filed under Fed. R. Civ. P. 12(b)(6), the Court must assume that all factual allegations in the complaint are true. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Legal conclusions "must be supported by factual allegations" and "are not entitled to the assumption of truth." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

In evaluating a motion to dismiss under Fed. R. Civ. P. 12(b)(6) (or Rule 12(c)), a court may consider the pleadings, exhibits attached to the pleadings, matters of public record, and any documents "integral to or explicitly relied upon" in the pleadings. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) ("[A] court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document.").

[4] [redacted]

Under Fed. R. Civ. P. 12(b)(1), a case may be dismissed for lack of subject matter jurisdiction. "Challenges to jurisdiction under Rule 12(b)(1) may be either facial or factual." *AstraZeneca AB v. Anchen Pharms. Inc.*, No. 11-2317, 2014 U.S. Dist. Lexis 79201, at *9 (D.N.J. June 11, 2014) (internal citation omitted). A facial attack challenges the sufficiency of the pleadings, but a court reviewing a factual challenge "may consider evidence outside the pleadings." *Gould Electronics Inc.*, 220 F.3d at 176. "The party invoking federal jurisdiction bears the burden of establishing [the] elements" required for jurisdiction. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992).

V. ARGUMENT

A. Counts V and VI of Plaintiffs' Third Amended Complaint Should Be Dismissed for Failure to State a Claim Upon which Relief Can Be Granted under Fed. R. Civ. P. 12(c)

Plaintiffs' counts for infringement of the '910 patent should be dismissed for failure to state a claim on the same reasons that the Court previously dismissed the polymorph patents. Just like the polymorph patents, Sandoz Inc.'s ANDA contains a Paragraph III certification for the '910 patent. In fact, the only reason Sandoz did not include the '910 patent in its prior motion for partial judgment on the pleadings was timing. Sandoz did not convert to Paragraph III for the '910 patent until December 4, 2019, which was after briefing on its motion was completed in September 2019. [redacted] D.I. 605.

1. The Court's Opinion Dismissing the Polymorph Patents in View of Sandoz's Paragraph III Certifications Applies Equally to Sandoz's Paragraph III Certification for the '910 Patent

The same reasoning that the Court applied in dismissing the polymorph patents applies to the '910 patent. D.I. 813, Op. at 8-12. For example, the Court observed that the Plaintiffs' complaint predicated infringement of the polymorph patents on Sandoz seeking FDA approval to engage in the commercial manufacture, use, or sale of vortioxetine "before the expiration of

[each polymorph] patent." *Id.* at 8. Similarly, Plaintiffs' Third Amended Complaint alleges that Sandoz will infringe the '910 patent by "seeking FDA approval of a generic version of TRINTELLIX® ***prior to*** the expiration of the '910 patent." D.I. 809, ¶ 115 (emphasis added); *see also id.*, ¶ 130 ("Defendants' infringing activity, including the commercial manufacture, use, offer for sale, sale, or importation of Defendants' ANDA Products, will begin immediately after the FDA approves Defendants' ANDA. Any such conduct ***before the '910 Patent expires*** would contribute to the direct infringement of one or more claims of the '910 Patent . . . ." (emphasis added)). Just like the polymorph patents, Sandoz's Paragraph III certification for the '910 patent "created circumstances under which the FDA will only approve its ANDA ***after*** the ['910] patent has expired." D.I. 813, Op. at 8 (quoting *Amerigan Pharm. Ltd. v. UCB Pharma GmbH*, 913 F.3d 1076, 1083 (Fed. Cir. 2019) (internal quotation marks omitted)). Accordingly, just like the counts alleging infringement of the polymorph patents, Counts V and VI alleging infringement of the '910 patent should be dismissed for failure to state a claim on which relief may be granted.

Just as with the polymorph patents, this conclusion is confirmed by the fact that Sandoz Inc.'s Paragraph III certification for the '910 patent already provides Plaintiffs with the only relief to which they might be entitled. As the Court correctly noted in its opinion regarding the polymorph patents, "the remedy for a prevailing plaintiff [on a claim for infringement brought under § 271(e)(2)] is an injunction delaying approval of a defendant's ANDA until expiration of all listed Orange Book patents." *Id.* at 9 (quoting *AstraZeneca AB v. Aurobindo Pharma Ltd.*, No. 11-cv-2317, 2014 U.S. Dist. Lexis 79201, at *16 (D. Del. Sept. 15, 2016) (internal quotation marks omitted)). Indeed, Plaintiffs' Third Amended Complaint seeks, "[a]n order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Defendants' ANDA shall be no earlier than the last expiration date of . . . the . . . '910 Patent[ ]." D.I. 809, Third Am.

Compl. at 36. "Sandoz, by converting from Paragraph IV to Paragraph III, has already essentially given Plaintiffs what they asked for from the Court" and "[t]here is no additional relief the Court can now provide." D.I. 813, Op. at 9.

The only factual difference between Sandoz's certification for the '910 patent and the previously-dismissed polymorph patents is that Sandoz ***never*** certified under Paragraph IV for the '910 patent. Sandoz's original certification for the '910 patent was a section viii statement rather than a Paragraph IV certification. [redacted] In *AstraZeneca Pharmaceuticals L.P. v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012), the Federal Circuit held that AstraZeneca had failed to state a claim for relief where defendants had submitted section viii statements – like Sandoz's original certification for the '910 patent – rather than Paragraph IV certifications. *Id.* at 1377-78. Thus, if anything, the fact that Sandoz's prior certification for the '910 patent was under section viii – not Paragraph IV – makes the case for dismissal of this patent even stronger than for the polymorph patents.

2. Plaintiffs' Duplicative Declaratory Judgment Count for the '910 Patent Does Not State a Claim Given Sandoz's Paragraph III Certification

Plaintiffs attempt to distinguish the '910 patent from the previously-dismissed polymorph patents based on their allegations of infringement under the Declaratory Judgment Act. D.I. 839, Joint Status Rep. at 1. In addition to a count for infringement under section 271(e)(2) (Count V), Plaintiffs' Third Amended Complaint also includes a separate count for infringement of the '910 patent under the Declaratory Judgment Act (Count VI). Notably, the allegations in Counts V and VI are almost identical, except that the latter purports to be raised under Declaratory Judgment Act. *See* Appendix 1 (showing Count V-VI allegations side-by-side), attached hereto. There are no allegations in Count VI to suggest a real or immediate dispute that could give rise to declaratory judgment jurisdiction – just allegations that Sandoz's infringement "will begin

immediately ***after*** the FDA approves Defendants' ANDA." Appendix 1, ¶ 130; D.I. 809, ¶ 130. There are multiple problems with Plaintiffs' reliance on this duplicative declaratory judgment count to distinguish the '910 patent from the polymorph patents that the Court has already dismissed.

First, Plaintiffs' own complaint alleges only that Sandoz will infringe the '910 patent under the Declaratory Judgment Act "upon FDA approval" of the ANDA. D.I. 809, ¶¶ 125-26, 128-30. As a result of Sandoz's Paragraph III certification for the '910 patent, the FDA cannot approve Sandoz's ANDA prior to expiration of the '910 patent and Sandoz cannot infringe the '910 patent.

Second, Plaintiffs ignore that the Court only granted Plaintiffs' motion to amend to add the '910 patent to the suit based on the existence of a live controversy as to the four polymorph patents that Sandoz was then challenging via Paragraph IV certifications. Ex. G, May 29, 2019 Hr'g Tr. 14:20-16:10. The Court reasoned that because, "[i]t's undisputed that defendants are litigating these cases, are making preparations to market and manufacture their proposed products," it was appropriate to grant Plaintiffs' motion to amend to add the '910 patent to the suit. *Id.* The circumstances have changed as to Sandoz. Sandoz has withdrawn all its Paragraph IV certifications and the polymorph patents have been dismissed from the suit. [redacted] D.I. 813. There is no longer any possible claim that a related case or controversy exists involving Sandoz's ANDA No. 210993 and the polymorph patents. As such, the '910 patent should also be dismissed.

Third, Plaintiffs' duplicative declaratory judgment counts for alleged contributory infringement of the non-MDD patents cannot cure their failure to state a claim under section 271(e)(2). The Declaratory Judgment Act is not an end run around the requirements for suit

under section 271(e)(2). The Hatch-Waxman Act allows for suit under § 271(e)(2) precisely because patent infringement claims based on the filing of an ANDA seeking FDA approval years later lack "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *See MedImmune, Inc. v. Genentech, Inc*., 549 U.S. 118, 127 (2007) (internal citation and quotations omitted). "[S]ection 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed." *Allergan, Inc. v. Alcon Labs., Inc.,* 324 F.3d 1322, 1330 (Fed. Cir. 2003). Indeed, numerous courts have dismissed duplicative declaratory judgment counts like Count VI even where they are paired with a proper count under section 271(e)(2). *See Noven Therapeutics, LLC v. Actavis Labs. FL, Inc.*, No. 14-6414, 2015 U.S. Dist. Lexis 175628, at *4 (D.N.J. Feb. 20, 2015) (declining to exercise jurisdiction over duplicative declaratory judgment counts); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 938-39 (N.D. Ill. 1995) (declining to exercise jurisdiction over § 271(a) claim when it would "undermine" Congress's policy in enacting Hatch-Waxman and because a controversy would materialize only after FDA approval and generic marketing); *Takeda Pharm. Co. v. Mylan Inc.*, 62 F. Supp. 3d 1115, 1127 (N.D. Cal. 2014) ("permitting Takeda to proceed on [its declaratory judgment count] appears unnecessary in light of (if not contrary to) the Hatch-Waxman Act"). Given that Sandoz has submitted a Paragraph III certification for the '910 patent and thus no count can be asserted under section 271(e)(2), it would be even more inappropriate for the suit to proceed solely on the basis of Plaintiffs' Declaratory Judgment count.

B. Counts V and VI of Plaintiffs' Third Amended Complaint Should Be Dismissed for Lack of Subject Matter Jurisdiction under Fed. R. Civ. P. 12(b)(1)

Plaintiffs' counts alleging infringement of the '910 patent should be dismissed for the additional reason that Sandoz's Paragraph III certification for the '910 patent leaves the Court without jurisdiction under either section 271(e)(2) or the Declaratory Judgment Act.[5]

As a result of Sandoz's Paragraph III certification for the '910 patent, Plaintiffs' Counts V and VI suffer from a lack of standing sufficient to meet the case-or-controversy requirement of Article III. The "irreducible constitutional minimum of standing" requires demonstration of three elements: (1) an injury in fact; (2) a causal connection between the injury and the conduct complained of; and (3) a likelihood that the injury will be "redressed by a favorable decision." *Lujan*, 504 U.S. at 560-61. As the party invoking federal jurisdiction, Plaintiffs bear the burden of establishing each element. *Id.* at 561. Here, Plaintiffs cannot meet that burden.

1. Plaintiffs Cannot Establish An Injury in Fact in View of Sandoz's Paragraph III Certification for the '910 Patent

Plaintiffs' first insurmountable hurdle to establishing Article III standing for Counts V and VI is the injury in fact requirement. The Supreme Court has defined an injury in fact as "an invasion of a legally protected interest which is (a) concrete and particularized . . . and (b) actual or imminent, not 'conjectural' or 'hypothetical.'" *Lujan*, 504 U.S. at 560.

Plaintiffs' alleged injuries flow from their allegations that Sandoz will commercially manufacture, sell, or offer for sale its ANDA product before the expiration of the '910 patent.

[5] The Court previously ruled that subject matter jurisdiction exists notwithstanding Sandoz's section viii statement for the '910 patent. D.I. 260; Ex. G, 5/29/19 Hr'g Tr. 6-15. In view of Sandoz's Paragraph III certification for the '910 patent in December 2019, circumstances have changed materially since the Court ruled on this issue earlier in 2019.

D.I. 809, ¶¶ 125-26, 128-30. With Sandoz's conversion to Paragraph III, Sandoz is now requesting approval as "of the date on which [the '910] patent ***will expire***" – not before. 21 U.S.C. § 355(j)(2)(A)(vii)(III), (5)(B)(ii).

The facts that caused the Court to deny Sandoz's prior motion to dismiss the polymorph patents based on lack of subject matter jurisdiction do not exist with respect to the '910 patent. For the polymorph patents, the Court was persuaded that its subject matter jurisdiction was established by Plaintiffs filing suit for infringement based on Sandoz's original Paragraph IV certifications for the polymorph patents. D.I. 813, Op. 7. The Court reasoned that "the Court's jurisdiction did not disappear when Sandoz converted its Paragraph IV certifications to Paragraph III certifications." *Id*. The Court further found that Sandoz's conversion from Paragraph IV to Paragraph III did not moot the existing case or controversy because Sandoz had not agreed to forego a future Paragraph IV certification. *Id.* By contrast, Sandoz has never submitted a Paragraph IV certification for the '910 patent. [redacted] As a result, there is no original case-or-controversy related to the '910 patent that Plaintiffs can point back to now. Nor is there any dispute over whether Sandoz will file a new Paragraph IV certification for the '910 patent.

The Court's finding of subject matter jurisdiction over the polymorph patents does not apply to the '910 patent for the additional reason that Plaintiffs have never identified an independent case-or-controversy for the '910 patent standing alone. In arguing for jurisdiction over the '910 and '096 patents, Plaintiffs pointed to the parties' dispute over the polymorph patents, arguing "[i]t is in the interest of the Court and the parties to try Plaintiffs' claims relating to the '910 and '096 Patents only once, and to resolve all infringement disputes prior to approval of Defendants' ANDA Products . . . ." D.I. 242, Pls. Ltr. at 2-3. Similarly, the Court's

comments accompanying its grant of Plaintiffs' motion to amend to add the '910 patent indicate the Court was swayed to allow the additional claims related to the '910 patent based on the existing dispute at that time related to the polymorph patents. Ex. G, 5/29/19 Hr'g Tr. 14:24 ("I'm not prepared to say that the dispute between the parties isn't ripe enough or isn't immediate enough. It's undisputed that defendants are litigating these cases, are making preparations to market and manufacture their proposed products."). With the Court's dismissal of Plaintiffs' counts alleging infringement of the polymorph patents on June 26, 2020, there is no longer a live dispute between the parties related to the polymorph patents. The '910 patent should also be dismissed because no case-or-controversy exists for the '910 patent independent of the now-dismissed polymorph patent dispute.

2. Plaintiffs Cannot Establish a Redressable Injury Sufficient for Standing in Light of Sandoz's Paragraph III Certification for the '910 Patent

In addition to a concrete injury, in order to establish standing, Plaintiffs must also demonstrate that its injury "is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). Plaintiffs cannot meet their burden to show that any of their alleged injuries related to Counts V and VI are "likely to be redressed by a favorable judicial decision" for two reasons.

First, the remedies available under the Hatch-Waxman Act for Counts V and VI allow for no relief other than what Takeda has already achieved by virtue of Sandoz Inc.'s Paragraph III certification for the '910 patent. *See id*. "[T]he remedy for a prevailing plaintiff [in a Hatch-Waxman case] is an injunction delaying approval of a defendant's ANDA ***until expiration of all listed Orange Book patents***." *AstraZeneca AB*, 2014 U.S. Dist. Lexis 79201, at *16 (emphasis added). With the Paragraph III certification, FDA cannot approve the ANDA until the '910 patent expires. Thus, while just short of a formal injunction, delay in final approval of the

ANDA is exactly what Sandoz Inc.'s Paragraph III certification has already accomplished. *Id.* ("Defendant's [Paragraph III] amendment effectively gives Plaintiffs the relief that would have been available to them were this case to proceed.").

Second, even if Plaintiffs were to obtain an injunction against Sandoz preventing the FDA from approving Sandoz's ANDA No. 210993 it would not resolve anything. At the time Plaintiffs originally added counts alleging infringement of the '910 patent to the suit, Sandoz had submitted a section viii statement [redacted] that had allowed Plaintiffs to add the '910 patent to the Orange Book. [redacted]; *see* 21 C.F.R. § 314.53(c)(ii); *id.* § 314.94(a)(2)(vi). Plaintiffs alleged that Sandoz's ANDA product would contributorily infringe the '910 patent notwithstanding that carve out. With Sandoz's submission of a Paragraph III certification for the '910 patent, Sandoz withdrew its carve-out for the '910 patent. [redacted] Going through the remainder of expert discovery and trial with Sandoz's [redacted] will not resolve whether Sandoz's ANDA would infringe if Sandoz were to later submit a new section viii statement and carve-out.

In sum, Plaintiffs now have no redressable injury in fact, and as a result, Plaintiffs lack standing such that the infringement counts should be dismissed.

VI. CONCLUSION

For the foregoing reasons, Sandoz respectfully requests that the Court dismiss Counts V and VI of Plaintiffs' Third Amended Complaint in their entirety without prejudice and grant Sandoz's motion.

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/*s/ Dominick T. Gattuso*
Dominick T. Gattuso (#3630)
HEYMAN ENERIO GATTUSO & HIRZEL LLP
300 Delaware Ave., Suite 200
Wilmington, DE 19801
dgattuso@hegh.law
Phone: (302) 472-7311

Attorneys for Defendants Sandoz Inc. and Lek Pharmaceuticals d.d.

OF COUNSEL:

Mark H. Remus
Laura A. Lydigsen
Jason Schigelone
Jieun Lee
BRINKS GILSON & LIONE
455 North Cityfront Plaza Drive, Suite 3600
Chicago, Illinois 60611-5599
mremus@brinksgilson.com
llydigsen@brinksgilson.com
jschigelone@brinksgilson.com
jlee@brinksgilson.com
Phone: (312) 321-4200

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APPENDIX 1: COUNTS V-VI OF PLAINTIFFS' THIRD AMENDED COMPLAINT

Count V	Count VI
108. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–107 as if fully set forth herein.	120. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–119 as if fully set forth herein.
	121. Plaintiffs' claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
109. On information and belief, Defendants submitted or caused the submission of ANDA No. 210993 to FDA, and thereby seek FDA approval of Defendants' ANDA Products.	122. On information and belief, Defendants submitted or caused the submission of ANDA No. 210993 to FDA, and thereby seek FDA approval of Defendants' ANDA Products.
110. Plaintiffs own all rights, title, and interest in and to the '910 Patent.	123. Plaintiffs own all rights, title, and interest in and to the '910 Patent.
111. The use of the ANDA Products falls within one or more claims of the '910 Patent.	124. The use of the ANDA Products falls within one or more claims of the '910 Patent.
112. On information and belief, upon FDA approval, the ANDA Products will be indicated for a single indication, the treatment of major depressive disorder.	125. On information and belief, upon FDA approval, the ANDA Products will be indicated for a single indication, the treatment of major depressive disorder.
113. Upon FDA approval, the ANDA Products will be used to treat cognitive impairment involving decline in speed of processing, executive function, attention, or verbal learning and memory in a patient diagnosed with depression.	126. Upon FDA approval, the ANDA Products will be used to treat cognitive impairment involving decline in speed of processing, executive function, attention, or verbal learning and memory in a patient diagnosed with depression.
114. The ANDA Products contain a pharmaceutically acceptable salt of vortioxetine (i.e., vortioxetine hydrobromide).	127. The ANDA Products contain a pharmaceutically acceptable salt of vortioxetine (i.e., vortioxetine hydrobromide).

115. Defendants have infringed one or more claims of the '910 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210993 and thereby seeking FDA approval of a generic version of TRINTELLIX® prior to the expiration of the '910 Patent.	
116. [redacted]	128. [redacted]
117. [redacted]	129. [redacted]
	130. [redacted]

	131. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '910 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.
118. This case is "exceptional" as that term is set forth in 35 U.S.C. § 285, and this entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.	132. This case is "exceptional" as that term is set forth in 35 U.S.C. § 285, and this entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.
119. [redacted]	133. [redacted]

CERTIFICATE OF SERVICE

I, Dominick T. Gattuso, Esquire, hereby certify that, on August 19, 2020, a copy of Defendants Sandoz Inc. And Lek Pharmaceuticals D.D.'S Opening Brief in Support of Their Motion for Partial Judgment On The Pleadings As To Counts V-VI of Plaintiffs' Third Amended Complaint and To Dismiss For Lack Of Subject Matter Jurisdiction was served upon all counsel of record via electronic mail.

/s/ *Dominick T. Gattuso*
Dominick T. Gattuso (# 3630)